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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,683	04/13/2000	Patrick Rivelli JR.	5877-0001.32	7036

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.		Applicant(s)	
	09/548,683		RIVELLI, PATRICK	
	Examiner		Art Unit	
	Julian W. Woo		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 1, "the helical ribbon" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sawyer (5,108,417). Sawyer, in figure 3, in col. 4, lines 14-25, and in col. 5, lines 3-11, disclose the method of treating a lesion as claimed, where a stent inherently has a bending-stiffness gradient due to a gradient of ribbon thickness.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer in view of Poncet (5,833,694). Sawyer discloses the method substantially as claimed, but does not disclose a stent that is releasably attached to a pusher wire. Sawyer also does not disclose stent diameters in the contracted-condition and the fully expanded position as claimed in claim 4, nor does Sawyer disclose, as claimed in claim 5, the surface area of a vessel region containing the stent. Poncet teaches, in figures 1-3, a stent being delivered to a vessel with a pusher wire (22). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Poncet, to apply a pusher wire in the delivery of Sawyer's stent to a vessel. Such a wire in a catheter would permit accurate placement of a stent within a vessel without complete withdrawal of any part of the catheter from the patient's body. Also, it would have been a matter of design choice to dimension (diameter and length) a stent as claimed in the contracted -condition and the fully expanded position, so that a surface area in a vessel region, as claimed, would be covered by the stent. The choice of a stent size would be dependent upon the type and size of the vessel being treated and the size of a lesion being supported.

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6. Claims 1, 5, and 6 are rejected 35 U.S.C. 103(a) as being unpatentable over Kropf (4,760,849) in view of Poncet. Kropf, in figure 4, in col. 2, lines 50-59, in col. 3, lines 8-20, and in col. 4, lines 9-20, discloses a method of treating a lesion with a stent having a bending-stiffness gradient due to a gradient of ribbon width. Kropf's stent has dimensions as claimed in claims 5 and 6. For example, Kropf's stent can have a stent ribbon thickness of .5 mils; a lesser ribbon width (at midsection 11) of 5 mils (i.e., 2.5 mils of spring material width + 2.5 mils of opening width as seen in figure 4); and a greater ribbon width (at endsection 17 or 19), which is at least 10 times the ribbon thickness and at least two times the lesser width. However, Kropf does not specifically disclose guiding a catheter to a target site. Poncet teaches a the guidance of a catheter to a target site for the deployment of a stent. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Poncet, to apply a catheter with the method of Kropf. Such a catheter would allow the safe delivery of a stent to a target site without undue damage to the vessel wall as the stent traverses the lumen of the vessel.

Allowable Subject Matter

7. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses stent openings that are I-beam shaped or Z-shaped, where each of the "I" axis and the

central axis of the "Z" is transversely aligned to the longitudinal axis of the stent in its contracted state.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

Applicant's arguments filed on September 25, 2002 have been fully considered but they are not persuasive.

With respect to arguments regarding the Sawyer reference: A stent is advanced through the catheter at preassembly *and* deployment (see U.S. Patent No. 4,665,918, which was incorporated by reference in col. 5, lines 3-6). In col. 4, lines 4-6, Sawyer discloses a stent made from a "flat strip of titanium or aluminum." A "flat strip" is synonymous with "ribbon."

With respect to arguments regarding the references of Sawyer in view of Poncet: "Advancing through the catheter the stent" is performed at deployment of the stent, not only at preassembly of the catheter and the stent.

With respect to arguments regarding the references of Kropf in view of Poncet: Kropf does disclose a gradient of width. That is, in figure 4, between the middle section (11) and each of the end sections (17, 19), a transitional section of the blank exemplifies a gradual increase in width from the middle section to the end section. A bending stiffness gradient inherently results from the changing cross-sectional dimensions of the blank along its length. Also, the coil of figure 5 of Kropf does have a length, and it is a

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stent for "support[ing] deficit blood vessels or to stabilize respiratory tract and brochi" (see col. 4, lines 16-26). Finally, to restate: Kropf discloses a stent for intraluminal implantation, but, as the Applicant concurs, does not disclose the mode of implantation. However, as taught by Poncet, advancement of a stent through a catheter is a well-known method of implantation. Thus, Kropf in view of Poncet obviates the invention as claimed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.



Julian W. Woo
Patent Examiner

November 20, 2002